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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,646	03/15/2002	Kenneth C. Waterman	PC11851AAKM	2293

7590 10/19/2004  
Gregg C. Benson  
Pfizer Inc.  
Patent Department, MS 4159  
Eastern Point Road  
Groton, CT 06340

EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/099,646

Applicant(s)

WATERMAN, KENNETH C.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-18,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8-18,20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on June 28, 2004.

Claims 1-3, 8-18, 20 and 21 are pending.

#### *Withdrawal of Rejections from Previous Office Action*

- The anticipatory rejections over Green et al and Hekal are withdrawn in view of Applicants' amendment to define the oxygen absorber as being UV activated into the independent claims. Likewise, the obviousness rejection over Hekal in view of Green et al is withdrawn

#### *Drawings*

The drawings were received on June 28, 2004. These drawings are acceptable.

#### *Claim Observations*

- Claim 18 contains two occurrences of the term "verapamil" (at line 4 and again at line 7). The second occurrence of the term should be deleted.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 11-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al in view of US Patent 6,139,770 to Katsumoto et al.

Green et al teach a package for containing drugs or medicaments wherein the shelf-life

of the drugs is increased. The package comprises a first laminate material (30) that becomes the lid for the package. A second laminate material (32) forms the recess/well in which the drug (100) is contained. A heat-seal coating is provided on laminate (30). The first and second laminate materials are heat sealed to form a reservoir having each individual drug dose (100) sealed there between (col. 3, lines 18-45; figure 2. At col. 5, lines 1-7, Green et al teach that an oxygen scavenger (oxygen absorber) may be incorporated into the package to remove oxygen, as recited in claim 1. With respect to claims 11, 13 and 18, Green et al teach epinephrine, dobutamine and dopamine as drugs that can be stored in the package. Epinephrine has a pKa of 6.3, as recited in claims 14-15.

Green et al differ from the instant invention in that there is no disclosure of using UV activated oxygen absorbers and there is no disclosure of specific shelf-life ability of the packaging materials.

Katsumoto et al teach an oxygen scavenging system for use in packaging containing products that are sensitive to oxygen, such as food and pharmaceuticals, to allow the product to have an improved shelf life. The oxygen scavenger of Katsumoto et al comprise photoinitiators to allow the oxygen scavenger to be activated by UV light (col. 8, lines 22-38). Katsumoto et al teach that the oxygen scavengers scavenge at least 0.1 cc O<sub>2</sub>/gram of oxygen scavenging composition/day (col. 7, lines 36-45), thus allowing the stored product to have an improved shelf life prior to activation. Table 1 of Katsumoto et al show UV activated oxygen scavengers that were initiated quickly (one minute) and that removed most all oxygen in as little as two days.

It would have been obvious to one of ordinary skill in the art to use the UV-activated oxygen scavengers of Katsumoto et al in place of those taught by Green et al to provide an

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effective manner of removing oxygen from oxygen-sensitive products, which can be activated quickly with UV light and which provides an improved shelf life for the product. With respect to minimizing degradation and/or discoloration of the product, it is the position of the Examiner that the decreased oxygen exposure, as a result of using the UV activated oxygen absorber, would also aid in minimizing degradation and/or discoloration.

3. Claims 1-3, 8-10, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hekal in view of Katsumoto et al.

Hekal teaches a barrier pack for storing single doses of medicine, in the form of a tablet, pill or capsule, that provides enhanced protection against contamination. The pack comprises a base portion (10) and a cover portion (20). The base (10) and cover (20) are heat sealed together. A cavity/recess (24) is formed into the cover (20) to contain the pharmaceutical product (4). See col. 3, lines 41-64. A layer having oxygen absorbing capability is also formed into the package, as recited in claim 1 (col. 2, lines 33-48). With respect to claim 2, Hekal teaches that the absorbing layer is placed between a first layer and a second layer of a three-layer composite (col. 8, lines 57-67). With respect to claim 3, Hekal teaches that the absorbing agent may also be formed into the individual cavities or may be formed into the both the cover composite layers and the cavities (col. 9, lines 4-24).

Hekal differ from the instant invention in that there is no disclosure of using UV activated oxygen absorbers and there is no disclosure of specific shelf-life ability of the packaging materials.

Katsumoto et al teach an oxygen scavenging system for use in packaging containing products that are sensitive to oxygen, such as food and pharmaceuticals, to allow the product to

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have an improved shelf life. The oxygen scavenger of Katsumoto et al comprise photoinitiators to allow the oxygen scavenger to be activated by UV light (col. 8, lines 22-38). Katsumoto et al teach that the oxygen scavengers scavenge at least 0.1 cc O<sub>2</sub>/gram of oxygen scavenging composition/day (col. 7, lines 36-45), thus allowing the stored product to have an improved shelf life prior to activation. Table 1 of Katsumoto et al show UV activated oxygen scavengers that were initiated quickly (one minute) and that removed most all oxygen in as little as two days.

It would have been obvious to one of ordinary skill in the art to use the UV-activated oxygen scavengers of Katsumoto et al in place of those taught by Hekal to provide an effective manner of removing oxygen from oxygen-sensitive products, which can be activated quickly with UV light and which provides an improved shelf life for the product. With respect to minimizing degradation and/or discoloration of the product, it is the position of the Examiner that the decreased oxygen exposure, as a result of using the UV activated oxygen absorber, would also aid in minimizing degradation and/or discoloration.

#### *Response to Arguments*

4. Applicant's arguments with respect to claims 1-3, 8-18, 20 and 21 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jill Warden  
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